



United States Department of the Interior

FISH AND WILDLIFE SERVICE

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Docket No. 97N-0217
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TO: FDA's Dockets Management Branch (HFA-305)
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Comments for the Discussion Draft of Proposals to Increase the Availability of Approved Animal Drugs for Minor Species and Minor Uses:

Proposal A. Modification of Extralabel Provisions

The proposal to modify the extralabel provisions with a sunset period would greatly benefit the aquaculture industry. It would not serve as a disincentive to the pursuit of approvals since the sunset period would only last for a set period of time, 10 years. In this way, the incentive to pursue drug approvals would remain. This provision would help provide temporary relief for the great lack of approved drugs in aquaculture. In addition, it would help prevent animal suffering and mortality during the waiting period until more drugs are approved for use in aquaculture.

These proposed modifications should be extended to include reproductive hormones and implants as long as the fish implanted or injected are not used for food.

Proposal F. Creation by Statute of a "Minor Use Animal Drug" Program

In this proposal, a statutory designation of "minor use animal drug" similar to the statutory designation of "human orphan drug" makes sense. Since the orphan drug program is already functioning and has shown great success, it makes sense to pattern the minor use animal drug program in

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the same way. The incentives associated with this strategy are necessary

for drug companies to be interested in minor use animal drugs since this market is so small and provides very little financial incentive for sponsorship or development of new drugs on its own.

Proposal G. Conditional Drug Approval for Minor Uses Involving Non-food Animals

Within this proposal, non-food life stages should be included. As in the case of aquaculture, especially with anadromous fish, fish are released to migrate to the ocean and will not be of catchable or consumable size for a minimum of 18 months. In this way, the life stages involved as the fish are raised from eggs to smolts could be considered non-food life stages and treated with medications accordingly.